

REMARKS

On page 5 of the Office Action dated October 4, 2005, the Examiner objects to the Abstract of the Disclosure. Applicant herewith submits amendments to overcome the objections and respectfully requests the Examiner withdraw the objection. No new matter has been added by way of the amendments.

On page 5 of the Office Action, the Examiner notes the use of trademarks in the disclosure and recommends capitalization and use of generic terminology in connection with same. Applicant herewith submits amendments directed to the use of trademarks in the disclosure. No new matter has been added by way of the amendments.

With respect to the provisional election of group III, claims 13-22, directed to a test kit for performing an assay, classified in class 422, subclass 61, Applicant confirms the election, with traverse. Consequently, claims 1-5 (Group I) and claims 6-12 (Group II) are herewith withdrawn. However, Applicant respectfully points out that claims 6-12 (Group II) include all limitations of claims 13-22, as amended. Thus, Applicant respectfully requests that the Examiner rejoin claims 6-12 (Group II) upon the allowance of one or more claims of appropriate scope in the present application.

Turning now to the substantive rejections, claims 13-22 are pending and stand rejected. In response to the Office Action claims 13, 17, 19, 20-21 have been amended and claim 16 is herewith cancelled. No new matter has been added by way of the amendments. Reexamination and reconsideration of the claims as requested is respectfully requested.

On page 5 of the Office Action, claims 13-22 are rejected under 35 U.S.C. §112, first paragraph, because it is the Examiner's position that the specification, while enabling for a test kit for detection of autoantibodies specific for intrinsic factor that

interfere with vitamin B12 binding to intrinsic factor ("type I" antibodies), does not reasonably enable kits for detection of all autoantibodies specific for all receptors with autoantibody binding sites. Applicant respectfully traverses this rejection by the amendments to the claims contained herein.

Consequently Applicant respectfully requests the Examiner withdraw the rejection of claims 13-22 under 35 U.S.C. §112, first paragraph.

On page 8 of the Office Action, claims 13-16 and 20-22 are rejected under 35 U.S.C. §102(e) as being anticipated by Newman (U.S. Patent No. 6,942,977) or, alternatively, Newman (CA Patent Application 2,110,109), collectively referred to hereinafter as "Newman". Applicant respectfully traverses this rejection.

To anticipate a claim, a reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their features, must be found in a cited reference to maintain a rejection based on 35 U.S.C. § 102.

Applicant asserts that the cited reference fails to teach every element of claim 13, and therefore fail to anticipate independent claim 13.

Claim 13, as amended, provides, *inter alia*, an interference blocking reagent that will specifically bind to vitamin B12 in the sample.

In the Office Action, the Examiner equates the interference blocking reagent of the present application to the dextran coated charcoal in Newman.

The present invention does not conform to the Examiner's characterization since claim 13, as amended, indicates that the interference blocking reagent will specifically bind to vitamin B12. In contrast, Newman simply employs a general charcoal adsorbent that will bind non-specifically to any number of substances in the sample.

For at least the reasons provided above, Applicant respectfully submits that Newman does not disclose the Applicant's invention as set forth in independent claim 13. Therefore, claim 13 is not anticipated by Newman, and is allowable over Newman.

Applicant respectfully requests withdrawal of the rejection of claim 13 under 35 U.S.C. § 102(e) as being anticipated by Newman.

Dependent claims 14-16 and 20-22, which are dependent from independent claim 13, are also rejected as being unpatentable over Newman. While the Applicants do not acquiesce to the particular rejections to these dependent claims, it is asserted that these rejections are moot in view of the remarks made in connection with independent claim 13. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from Newman.

Applicants respectfully request withdrawal of the rejection of claims 14-16 and 20-22 under 35 U.S.C. § 102(e) as being anticipated by Newman. On page 6 of the Office Action, claims 17-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Newman in view of Pourfarzaneh (US Patent No. 5,564,104). Applicant respectfully traverses this rejection.

Three criteria must be met to establish a prima facie case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the

reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142.

As discussed above, Newman fails to disclose and further fails to suggest to one skilled in the art the invention the use of an interference blocking reagent that is capable of specifically binding to vitamin B12 as claimed in independent claim 13.

Pourfarzaneh fails to cure the defects of Newman in this regard. Pourfarzaneh discloses a method for physically removing and/or separating radioactive waste from a solution. The goal of the cited reference is to eliminate the labeled material from solution altogether. By contrast, the present invention discloses and claims an interference blocking reagent that specifically binds to vitamin B12, without the need for physically removing all of the bound complex from solution as taught and suggested by Pourfarzaneh. As such, one skilled in the art would not find motivation to combine the two references as suggested by the Examiner. Similarly, Pourfarzaneh fails to teach or suggest, the use of an interference blocking reagent that specifically binds to vitamin B12 as claimed in independent claim 13.

Thus, neither Newman nor Pourfarzaneh, nor the combination thereof, teach or suggest the present invention as claimed in independent claim 13 and therefore, independent claim 13 is not obvious over Newman in view of Pourfarzaneh.

Dependent claims 17 and 18, which are dependent from independent claim 13, are the claims actually rejected as being unpatentable over Newman in view of Pourfarzaneh. While Applicant does not acquiesce to the particular rejections to these dependent claims, it is asserted that these rejections are moot in view of the remarks made in connection with independent claim 13. These dependent claims include all of

the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from Newman in view of Pourfarzaneh.

For at least the reasons set forth above, Applicant respectfully requests the Examiner withdraw the rejection of claims 17 and 18 under 35 U.S.C. §103(a) as being unpatentable over Newman in view of Pourfarzaneh.

On page 6 of the Office Action, claim 19 is rejected under 35 U.S.C. §103(a) as being unpatentable over Newman in view of Pourfarzaneh as applied to claims 17-18 above, and in further view of Herbert (US Patent No. 4,680,273). Applicant respectfully traverses this rejection.

As discussed above, Newman and Pourfarzaneh fail to provide motivation to one skilled in the art to combine the references and further fail to teach or suggest the elements of independent claim 13, as amended. Herbert fails to cure the defects of Newman and Pourfarzaneh in these regards.

Thus, the combination of Newman, Pourfarzaneh and Herbert fail teach or suggest the present invention as claimed in independent claim 13 and therefore, independent claim 13 is not obvious over Newman in view of Pourfarzaneh and in further view of Herbert.

Dependent claim 19, dependent from independent claim 13, is the claim actually rejected as being unpatentable over Newman in view of Pourfarzaneh in further view of Herbert. While Applicant does not acquiesce to the particular rejections to this dependent claim, it is asserted that this rejection is moot in view of the remarks made in connection with independent claim 13. Dependent claim 19 includes all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from Newman in view of Pourfarzaneh and in further view of Herbert.

For at least the reasons set forth above, Applicant respectfully requests the Examiner withdraw the rejection of claim 19 under 35 U.S.C. §103(a) as being unpatentable over Newman in view of Pourfarzaneh and in further view of Herbert.

On page 12 of the Office Action, claims 13-16 and 20-22 are rejected under 35 U.S.C. §103(a) as being unpatentable over publication by Smith in view of Newman. Applicant respectfully traverses this rejection.

As the Examiner admits, Smith fails to teach or suggest an interference blocking reagent that will specifically bind to vitamin B12 as claimed, *inter alia*, in independent claim 13. Contrary to the Examiner's assertion, and as discussed in detail above, Newman fails to cure at least this defect of Smith.

For at least the reasons set forth above, Applicant respectfully requests the Examiner withdraw the rejection of claim 13 under 35 U.S.C. §103(a) as being unpatentable over Smith in view of Newman.

Dependent claims 14-16 and 20-22, which are dependent from independent claim 13, are also rejected as being unpatentable over Smith in view of Newman. While Applicant does not acquiesce to the particular rejections to these dependent claims, it is asserted that these rejections are moot in view of the remarks made in connection with independent claim 13. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from Smith in view of Newman.

For at least the reasons set forth above, Applicant respectfully requests the Examiner withdraw the rejection of claims 14-16 and 20-22 under 35 U.S.C. §103(a) as being unpatentable over Smith in view of Newman.

On page 13 of the Office Action, claims 17-18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Smith in view of Newman as applied to claims 13-16 and 20-22 above, and further in view of Pourfarzaneh. Applicant respectfully traverses the rejection.

As discussed above, Smith, Newman and Pourfarzaneh, alone and in combination, fail to teach or suggest the elements of independent claim 13, as amended.

Dependent claims 17 and 18, dependent from independent claim 13, are the claims actually rejected as being unpatentable over Newman in view of Smith and in further view of Pourfarzaneh. While Applicant does not acquiesce to the particular rejections to these dependent claims, it is asserted that this rejection is moot in view of the remarks made in connection with independent claim 13. Dependent claims 17 and 18 include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from Smith in view of Newman in further view of Pourfarzaneh.

For at least the reasons set forth above, Applicant respectfully requests the Examiner withdraw the rejection of claims 17 and 18 under 35 U.S.C. §103(a) as being unpatentable over Smith in view of Newman and in further view of Pourfarzaneh.

On page 14 of the Office Action, claim 19 is rejected under 35 U.S.C. §103(a) as being unpatentable over Smith in view of Newman, and further in view of Pourfarzaneh as applied to claims 17 and 18 above. Applicant respectfully traverses the rejection.

As discussed above, Smith, Newman and Pourfarzaneh, alone and in combination, fail to teach or suggest the elements of independent claim 13, as amended.

Dependent claim 19, dependent from independent claim 13, is the claim actually rejected as being unpatentable over Newman in view of Smith and in further view of Pourfarzaneh. While Applicant does not acquiesce to the particular rejections to this dependent claim, it is asserted that this rejection is moot in view of the remarks made in connection with independent claim 13. Dependent claim 19 includes all of the limitations of the base claim and any intervening claims, and recites additional features which further distinguish this claim from Smith in view of Newman in further view of Pourfarzaneh.

For at least the reasons set forth above, Applicant respectfully requests the Examiner withdraw the rejection of claims 17 and 18 under 35 U.S.C. §103(a) as being unpatentable over Smith in view of Newman and in further view of Pourfarzaneh.

CONCLUSION

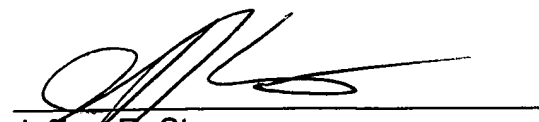
In view of the amendments and reasons provided above, it is maintained that all pending claims are in condition for allowance. The amendments clarify the patentable invention without adding new subject matter. Applicant respectfully requests favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicant's attorney of record, Jeffrey R. Stone at 952-253-4130 or M. Luke Alter at 305-380-3636.

Respectfully submitted,
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